

March 15, 1999

Mr. Joseph Levitt
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-001
200 C Street
Washington, DC 20204

RE: Removal or Reduction of an Ingredient from a Standardized Food

Dear Mr. Levitt:

In 1995 and 1996, the Calorie Control Council submitted two related Citizen Petitions to the Food and Drug Administration. The first, Docket No. 95P-0078, requests that food labeling regulations be amended to permit the removal of all or part of the fat from standardized foods even when fat is specifically required by the standard. The second, Docket No. 96P-1043/CP1, requests that food labeling regulations be amended to permit the removal or reduction of an ingredient of standardized foods even when the ingredient is specifically required by the standard. This petition specifically requests that 21 CFR 130.10(d)(4) be revised as follows:

An ingredient that is specifically required by the standard as defined in parts 131 through 169 of this chapter, shall be present in the product in a significant amount unless its absence or reduction is the permitted basis for the nutrient content descriptor used in the naming of the modified standardized food. A significant amount of an ingredient or component of an ingredient is at least the amount that is required to achieve the technical effect of that ingredient in the food.

The Calorie Control Council believes, after careful study of the issue, that in accordance with 21 CFR 130.10 in light of the FDA's "imitation" rule, 21 CFR 101.3(e), that standardized foods containing substantial amounts of fats or sugars can have the fat or sugar content significantly reduced or eliminated -- even if the standard specifically requires the ingredient.

95P-0078

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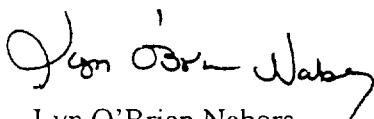
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The imitation rule provides that a product is an imitation if it is a substitute for and resembles another food and is nutritionally inferior to that food. Nutritional inferiority however "does not include a reduction in the caloric or fat content" of the food, so long as the food is nutritionally labeled and complies with any requirements with respect to special dietary foods under Part 105 (which also includes compliance with an appropriate nutrient content descriptor term). Thus a reduction in fat or a reduction in calories (from, for example, a reduction in sugar content) would not result in a product being nutritionally inferior and it would thus not be an "imitation" food.

The food would, however, in accordance with 21 CFR 101.3(e)(2) have to be named using an "appropriately descriptive term that is not false or misleading." As under Part 105 of FDA's regulations, applicable to caloric reductions, the term has to also be one that includes an approved nutrient content descriptor, such as "sugar free" or "fat free." It would, therefore, appear that this kind of modification would still fit within the generic standard. The generic standard looks to combining just such a mandatory nutrient descriptor with the name of a standardized food. This would be appropriate because the product would not be an imitation, and thus could be viewed as being the standardized food modified in accordance with the appropriate and approved nutrient content descriptor.

If the FDA does not object to this interpretation and so notifies the Calorie Control Council, the Council would be pleased to withdraw the two pending petitions mentioned above as they would be moot and no further FDA action on those petitions would be required.

Respectfully submitted,


Lyn O'Brien Nabors
Executive Vice President


Robert C. Gelardi
President

LONRCG/br